K100921

APR 30 2010

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

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Date Prepared: April 1, 2010

Device Information

Trade Name: ADMIRAL XTREME™ PTA Balloon Dilatation Catheter
Common Name: Percutaneous Transluminal Angioplasty Catheter
Regulation Name: Percutaneous Catheter

Predicate Device

Invatec ADMIRAL XTREME™ PTA Catheter (K062809)

Device Description

The ADMIRAL XTREME™ PTA Balloon Dilatation Catheter is an over-the-wire percutaneous transluminal angioplasty (PTA) catheter consisting of a proximal hub, dual lumen shaft, and a distal dilatation balloon. The ADMIRAL XTREME™ PTA Balloon Dilatation Catheter is compatible with guidewires with a maximum diameter of 0.035" and with 5, 6 or 7 FR introducer sheaths, depending on the diameter/length of the dilatation balloon. The catheter is

provided with a hydrophilic coating and is available in useable catheter lengths of 40cm, 80cm and 120cm.

Modified Device Description

The ADMIRAL XTREME™ PTA Balloon Dilatation Catheter includes additional balloon lengths of 150 mm, 200 mm, 250 mm and 300 mm. The modified ADMIRAL XTREME™ PTA Balloon Dilatation Catheter is manufactured from the same materials as the predicate ADMIRAL XTREME™ PTA Catheter and has the same Intended Use.

Indication for Use

The ADMIRAL XTREME™ PTA Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Technological Characteristics

The ADMIRAL XTREME™ PTA Balloon Dilatation Catheter has the same or similar design, materials and fundamental technology as the previously cleared ADMIRAL XTREME™ PTA Catheter. This modification provides the user with longer balloon lengths to be used in the peripheral arteries.

Performance Testing and Safety

Verification testing of the ADMIRAL XTREME™ PTA Balloon Dilatation Catheter demonstrated that the device met the acceptance criteria. Verification testing included catheter and balloon dimensional testing, minimum balloon burst strength (RBP), balloon compliance, balloon inflation and deflation time, balloon fatigue, tensile strength, flexibility and kink test, torque strength, balloon preparation, catheter body burst pressure, guidewire compatibility, introducer sheath compatibility, radiopacity, coating lubricity and coating durability.

There are no new materials used in the manufacture of the ADMIRAL XTREME™ PTA Balloon Dilatation Catheter. Biocompatibility requirements were previously met with the predicate device according to ISO 10993: Biological Evaluation of Medical Devices and the FDA Blue Book Memorandum #G95-1.

Conclusion

Based on the same intended use, similar technological characteristics, and performance characteristics, the ADMIRAL XTREME™ PTA Balloon Dilatation Catheter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 30 2010

Invatec S.p.A
c/o Peter Muster, Ph.D.
Vice President, Quality and Regulatory
Via Martiri della Liberta, 7
Roncadelle (Brescia), Italy 25030

Re: K100921
Trade/Device Name: ADMIRAL XTREME™ PTA Balloon Dilation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: April 01, 2010
Received: April 02, 2010

Dear Dr. Muster:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100921

Device Name: ADMIRAL XTREME™ PTA Balloon Dilatation Catheter

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100921